

for this purpose, since the products thus produced are too thick, do not flow, cake and/or are impossible to redisperse. Furthermore, even where such a product can be made, the taste is so objectionable that no patient could be persuaded to use it. A further disadvantage of aqueous systems is that they can act as hosts to microbial growth which, in turn, requires the use of bad tasting preservatives such as parabens and benzoates. Thus, the provision of a non-aqueous liquid suspension system would be desirable (col. 1, lines 30-44).

Furthermore, an essential component in Chavkin is a "pharmaceutically active" agent, which can be a mucosal bioadhesive. Chavkin states that polycarbophil is one such bioadhesive (col. 4, lines 7 to 19). Of polycarbophil Chavkin particularly points out:

It [polycarbophil] acts by absorbing water, forming a gel and promoting well-formed stools. The dose however is up to 6 grams per day for adults and 3 grams per day for children 6-12 years of age. It is marketed solely as chewable tablets of 0.5 grams, which are gritty and unpleasant to take. It is impossible to market an aqueous suspension, since by its nature, it would cause aqueous systems to gel (col. 3, lines 5 to 14).

Using the present invention it is possible to prepare fluid suspension containing 20% calcium polycarbophil. This suspension is very palatable and permits the easy administration of the large doses of polycarbophil necessary for optimum therapeutic efficacy (col. 3, lines 15-20).

Chavkin goes on to point out that other oil vehicles (other than those taught by Chavkin) for such suspensions have problems. Low viscosity edible oils have too high viscosity, which can be reduced with unsaturation but this causes rancidification and stability problems. Chavkin further points out that common suspending agents do not function well in the presence of high loadings of antacids in an oil medium (col. 1 line 52 to col. 2 line 17). Lastly, Chavkin has no examples that contain water.

Therefore, based on the above facts and arguments, Applicant traverses the 35 USC §102(b) rejection and respectfully requests withdrawal of this rejection.

35 USC § 103 Rejection

Claims 1-29 are rejected under 35 USC §103 as being unpatentable over Chavkin. To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art, *In re Royka*, 409 F. 2d 981, 180 U.S.P.Q. 580 (CCPA 1974). Chavkin, however, does not teach or suggest all claim limitations of the present invention. Chavkin only teaches non-aqueous compositions. This is supported by the above arguments. The present invention relates to aqueous compositions.²

Moreover, Chavkin teaches away from adding water into the compositions of Chavkin. An essential component in Chavkin is a "pharmaceutically active" agent, which can be a mucosal bioadhesive, such as polycarbophil (col. 4, lines 7 to 19). Of polycarbophil Chavkin particularly points out:

It [polycarbophil] acts by absorbing water, forming a gel and promoting well-formed stools. The dose however is up to 6 grams per day for adults and 3 grams per day for children 6-12 years of age. It is marketed solely as chewable tablets of 0.5 grams, which are gritty and unpleasant to take. It is impossible to market an aqueous suspension, since by its nature, it would cause aqueous systems to gel (col. 3, lines 5 to 14).

² See the Specification page 16, lines 24-26 and the Summary of the Invention, page 2.

Using the present invention it is possible to prepare fluid suspension containing 20% calcium polycarbophil. This suspension is very palatable and permits the easy administration of the large doses of polycarbophil necessary for optimum therapeutic efficacy (col. 3, lines 15-20).

Therefore, if one was to add water to the polycarbophil compositions disclosed in Chavkin, it would destroy the intended function of this composition. Therefore, the present invention is not obvious over Chavkin.

Claims 1-29 are also rejected under 35 USC §103 as being unpatentable over Chavkin further in view of Ponchel et al. The combination of Chavkin and Ponchel would not result in the claimed invention. Ponchel looks at the mechanism of action for the use of polymers (nano- and microparticulate polymeric systems, specifically polystyrene and polylactic acid) to improve oral delivery of drugs that are poorly soluble or bioavailable by the oral route (page 1- Introduction). The only carriers suggested by Ponchel, then, are polymers, not silica (which provides a mucoadhesive benefit for the present invention). Chavkin teaches non-aqueous liquid suspension systems for formulating active containing pharmaceutical compositions, where the administration of large quantities of the active is needed to achieve the therapeutic benefit. Chavkin teaches the use of oil vehicles with suspending agent to suspend these large quantities of actives. Furthermore, Chavkin only teaches non-aqueous suspensions and teaches away from adding water to the composition of Chavkin, as discussed above.

Therefore, the present invention is not obvious over Chavkin in view of Ponchel. Applicant respectfully requests removal of the obviousness rejections.

CONCLUSION

In view of the above arguments and facts all of the rejections are respectfully traversed or avoided. Applicant respectfully requests reconsideration of the application and allowance of all of the claims.

Respectfully submitted,
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